Testbiotech Data Factsheet:
Roundup Ready Soybean 40-3-2 (Monsanto)

January 2012

Plant:
Soybean

Event name:
Soybean 40-3-2

Applicant:
Monsanto

Trait:
Herbicide tolerance

Herbicide:
Glyphosate (brand name such as Roundup or Touchdown)

Transformation method:
Particle bombardment

Scope of application:
Food and feed, import and processing and cultivation

Impact on European market:
Millions of tons of genetically engineered soybeans are imported into the European market. Most of it is used in animal feed. Roundup Ready soybeans are not grown in the EU, but the application for cultivation is pending.

General information:
Roundup Ready Soybean 40-3-2 is one of the first genetically engineered plants that were cultivated commercially in the US and also introduced in other markets. It was the first product derived from genetically engineered plants that reached the European market in 1996. The reaction was a heated political debate in the EU that led to consumer rejection, mandatory labeling and segregation of the food market. While ingredients from Roundup Ready soy in food are avoided by nearly all European food producers, the feed sector imports millions of tons every year. However, some food companies in certain sectors of animal production such as the production of eggs and milk, also introduced a policy of avoiding the plants in animal feed. Furthermore, a voluntary legislation to label such products, which are being produced without genetically engineered plants, has been established in several EU countries.

Genetically engineered soybeans are made responsible for rain forest destruction in Argentina and Brazil as well as an overuse of herbicides in USA and South America. Joint initiatives, the so-called Round Table for Responsible Soy (RTRS), between companies such as Monsanto and the World Wide Fund For Nature (WWF), aimed to qualify soybeans as a part of sustainable agriculture but these were heavily criticized as 'green wash' by independent observers.

As weeds have become resistant to the spraying of glyphosate in many regions where these soybeans are cultivated, there has been a massive increase in usage of herbicides (Benbrook 2009;

Grube 2011). The extensive usage of glyphosate in herbicide resistant crops endangers the health of rural communities, aquatic systems, biodiversity and soil fertility, and it can cause plant diseases such as increased infestation with fungal diseases (Johal & Huber, 2009, Antoniou, et al., 2010; Paganelli et al., 2010; PAN AP 2009). The usage of glyphosate to spray genetically engineered soybeans also creates a risk for consumers by a mixture of potentially hazardous residues in the plants.

Several experts are warning that a higher toxicity has to be expected (Antoniou, et al., 2010; Benachour, et al., 2007; Paganelli et al., 2010; PAN AP 2009; Then 2011). In this context, the additive POEA also has to be taken into account as it is even more toxic than glyphosate in these plants. In 2010, German authorities even prohibited the usage of certain glyphosate formulations with a high content of POEA for the production of animal feeds in order to avoid a risk of toxins being passed through the food chain (Then, 2011). However, on the other hand, only very few controls are actually conducted within the EU market with the aim of finding residues that are left behind from spraying glyphosate formulations.

The GMO panel decided to leave these questions concerning the risk assessment of residues from spraying to EFSA´s pesticide panel. In parallel, there is an ongoing EU process which is reviewing glyphosate under the pesticide regulation. Results are expected in 2012 or even later (see EU Commission, 2002; Antoniou et al., 2011). Thus, the risk assessment of Roundup Ready soybeans suffers from two sides: From the work of the GMO panel and the European pesticide regulation. Nevertheless, EFSA gave a green light for the further marketing of Roundup ready soybeans in 2010 (EFSA 2010a).

Specific risks and unintended effects

- Plants contain residues from spraying with herbicide formulations and their metabolites.
- The method used to insert the gene sequence has several technical deficiencies e.g. a second non-functional copy of the gene construct was inserted into the plants.
- Open reading frames were identified that can give rise to unintended gene products in the plants (Rang et al., 2005).
- In comparison with its conventional counterparts, several significant differences in compositional analysis were observed. For example the lignin content in the plants is affected (Zobiole et al., 2010).
- In agronomic parameters, several significant differences were identified in comparison with the control plants. Lower yields are constantly observed and EFSA have also admitted this finding (2010a). Other differences were not consistent over all field trials. The reason for this might be that these differences only emerge under particular environmental conditions. Several investigations show that genetically engineered plants can exhibit unexpected reactions under stress conditions (see for example: Matthews et al., 2005, Gertz et al., 1999).
- Soybeans are known to cause severe allergic reactions. The newly introduced gene construct might, for example, enhance an immune response to these endogenous plant proteins.
- Soybeans are known to produce compounds with hormonal activity. The content of these compounds might be changed by interference with the newly introduced gene constructs.
- These plants will be fed and they will possibly be eaten together with other genetically engineered plants. Tests have to be performed on potential effects such as combinatorial or accumulated effects.
- Parts of the additional DNA was traced in animal tissue in fish and in milk from goats. The researchers even describe effects on offspring if these have been fed with milk from goats that have been fed with genetically engineered soybeans (Tudisco et al., 2010).

Type of feeding trial conducted:

- An acute toxicity study was performed, feeding isolated enzymes that enable tolerance to glyphosate. These proteins were not isolated from the plants but produced by bacteria.
- Several feeding studies with the plants were performed to assess health effects.
- Several feeding studies with the plants were performed to assess nutritional effects.

Overview on some shortcomings of EFSA's assessment:

- no assessment of risks posed by residues which stem from spraying the pesticide formulations and their metabolites was carried out
- no systematic investigation under various defined environmental conditions was conducted to determine interactions between the genome and the environment.
- there was no systematic investigation of changes in composition and agronomic performance under various defined environmental conditions.
- functional stability of the transgene under various defined environmental conditions was not shown. Genetic stability was only considered with regards the hereditary factors of the gene constructs for following generations.
- in comparison with its conventional counterparts, many significant differences in the compositional analysis were found. References were made to unspecific and questionable 'historical' data from industry which were unrelated to the actual field trials, e.g. the ILSI database. Since it is not sufficiently clear under which specific conditions this additional historical data was generated, this kind of comparison inevitably contains major uncertainties.
- Some feeding studies were longer than the normally performed 90-day feeding study. Even multi-generational studies were conducted. Some of these studies revealed effects that should have been investigated further (Malatesta et al., 2002a, 2002b, 2003, 2005, 2008). Instead EFSA dismissed the findings due to methodological issues.
- no investigations were conducted to assess the impact of a permanent ingestion of these plants on the intestinal microbial composition in humans and animals.
- no assessment of combinatorial effects with other genetically engineered plants used in food and feed was carried out.
- EFSA (2010a) is admitting that there was no monitoring of potential health effects, but nevertheless relies on the absence of evidence for adverse health effects for their conclusions: *"Although no post-market monitoring for food and feed safety of soybean 40-3-2 has formally been performed, there is no evidence of any adverse effects being associated with the consumption of soybean 40-3-2 as food or feed within the European community."*

Surveillance – Monitoring

- No plan for surveillance was made available that would allow identification of particular health impacts that might be related to the use of these genetically engineered plants in food and feed.
- Monitoring of health effects has to include the risks associated with the spraying of glyphosate formulations and their residues in the plants.

Documents and publications:

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